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10/749,150	12/30/2003	Marius Filtvedt	48577.2.1	3851
22859	7590	05/07/2007	EXAMINER	
INTELLECTUAL PROPERTY GROUP			PHAM, HUONG Q	
FREDRIKSON & BYRON, P.A.			ART UNIT	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/749,150	FILTVEDT ET AL.
	Examiner	Art Unit
	Huong Q. Pham	3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 15 February 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-27,29,30,32-52,54-67 and 69-82 is/are pending in the application.
- 4a) Of the above claim(s) 44-46, 59 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-27,29,30,32-43,47-52,54-58,60-67 and 69-82 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

**DETAILED ACTION**

Applicant's election in the reply filed on 12/13/2006 and 2/15/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

A complete reply to the final rejection must include cancellation of nonelected claims ( Group III, claims 44-46, 59) or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The Affidavit under 37 CFR 1.132 filed on 2/15/2007 is insufficient to overcome the rejection of all claims as set forth in the last Office action because: while applicant claims that negative pressure is generated for between 1 and 20 seconds and released for between 2 and 15 seconds, note that:

As for the MacLeod ( 3,292,613) 's patent, MacLeod ( 3,292,613) teaches that " the pressure can be synchronized to the heart beat or can be applied less or more frequently and in regular multiples of a heart beat , for example, during every second or third heart beat....., or the pressure can be applied irregularly with respect to the heartbeat."( column 5, lines 9-20). Therefore, the device of Macleod is capable of providing the recited pressures. Also, note that the rate of the heartbeat is different from one person to another. While the rate of the heartbeat of one person might be about every second or more, note that the rate of the heartbeat of another person (for

example, a person who is sleeping , or in a state of relaxation, or in a meditation state , etc.) might be much longer than one second. Also, note that the device of Macleod is capable of providing the recited pressures.

As for the Norton et al 's patent ( 3,878,839), note column 9, lines 63-68, and column 10, lines 1-21. Therefore , Norton et al 's device is capable of providing the recited negative pressure .

Also, note that a *prima facie* case of obviousness exists where the claimed ranges (or values ) and prior art ranges ( or values) do not overlap but are close enough that one skilled in the art would have expected them to have the same properties.

See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), and *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934. Also, see MPEP § 2131.03 for case law pertaining to rejections based on the anticipation of ranges under 35 U.S.C. 102 and 35 U.S.C. 102/103.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8, 11-16, 25, 29-30, 32- 34, 36-37, 52, 54, 57- 58, 60, 62 – 65, 69-78 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over MacLeod ( 3,292,613).

As for claim 1, by MacLeod teaches a device capable for applying a pulsating pressure to a local region of the body, the device comprising a pressure chamber 10 ( figure 1) in to which a limb of the body can be placed to seal it from external conditions, whereby in use the limb can be immersed in a liquid contained in the pressure chamber such that the liquid surrounds and is in contact with the limb , wherein an element 36 ( figure 1) is capable of generating pulses of pressure within the chamber that can be transmitted to the limb directly via the liquid. MacLeod ( 3,292,613) teaches that “ the pressure can be synchronized to the heart beat or can be applied less or more frequently and in regular multiples of a heart beat , for example, during every second or third heart beat....., or the pressure can be applied irregularly with respect to the heartbeat.”( column 5, lines 9-20). Therefore, the device of Macleod is capable of providing the recited pressures . Note that the rate of the heartbeat is different from one person to another. While the rate of the heartbeat of one person might be about every second or more, note that the rate of the heartbeat of another person (for example, a person who is sleeping , or in a state of relaxation, or in a meditation state , etc.) might be much longer than one second. Also, note that the device of Macleod is capable of providing the recited pressures.

As for claim 2, note seal 13. As for claim 3, note that the elongate housing 10 ( figure 1) is a cylindrical housing. As for claims 4-8, note the inlet and outlet 31, 42

provided in the housing 10 for introducing and discharging the liquid into and out of the chamber, liquid flow transmission means 26. As for claims 11-14, note means 36 is capable of generating pulses of pressure within the chamber and thereby exerting a pulsating pressure on the surface of the limb while the limb is immersed in a flow of liquid. As for claim 25, note that MacLeod teaches the recited steps including the steps of providing a pressure chamber; introducing a limb in to the pressure chamber such that it is sealed from external conditions, filling or partial filling the pressure chamber with a liquid to immerse the limb in the liquid so that it is substantially surrounded by and in contact with the liquid, and generating a pulsating pressure within the chamber and transmitting the pulses of pressure to the limb directly via the liquid. As for claim 34, note that the liquid is circulated within the pressure chamber to generate a flow of liquid which is in direct contact with the limb.

As for claim 15, note that the use of a Y connector to provide more connections between the pressure source and the chamber is well within the realm of one ordinary skill in the art ( note figure12 of Norton et al: 3,878,839) and does not provide any unobvious result, and therefore is not patentable over prior art. As for claims 29- 30, 32-33, 54, 64 –65, 69- 76, note that the claimed time intervals are results of obvious experiments and observations , which are well within the realm of one ordinary skill in the art, and do not provide any unobvious result, and therefore are not patentable over prior art. Note that MacLeod ( 3,292,613) teaches that “ the pressure can be synchronized to the heart beat or can be applied less or more frequently and in regular multiples of a heart beat , for example, during every second or third heart beat.....,

or the pressure can be applied irregularly with respect to the heartbeat." ( column 5, lines 9-20). Providing this teaching of MacLeod ( 3,292,613) wherein the pressure can be applied less frequently in regular multiples of a heartbeat ( i.e., in about at least more than one second , or longer), the exact optimum time intervals can be defined by obvious experiments and observations to provide optimum results, which are well within the realm of one ordinary skill in the art, and which do not provide any unexpected results, and therefore is not patentable over prior art.

Claims 9- 10, 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacLeod ( 3,292,613) in view of MacLeod (3,094,983) .

Note the comments above for the teaching of MacLeod (3,292,613) .

MacLeod (3,094,983) teaches a device capable for applying a pulsating pressure to a local region of the body, the device comprising a pressure chamber 10 ( figure 1) in to which a limb of the body can be placed to seal it from external conditions, heat exchanger 24, whereby in use the limb can be immersed in a liquid contained in the pressure chamber such that the liquid surrounds and is in contact with the limb , wherein an element 34 ( figure 1) is capable of generating pulses of pressure within the chamber that can be transmitted to the limb directly via the liquid, wherein the liquid is circulated through a heat exchanger unit 24. In view of the teaching of MacLeod (3,094,983) , it would have been obvious to one ordinary skill in the art at the time the invention was made to circulate the liquid in the chamber through a heat exchanger unit before it enters the pressure chamber in order to control the temperature of the liquid to be at the desired temperature for the patient.

As for claim 10, note that the use of a well-known heat exchanger which comprises a plurality of heat exchanger tubes housed within a water bath or reservoir is well within the realm of one ordinary skill in the art, and does not provide any unobvious result, and therefore is not patentable over prior art.

Claims 17- 18 , 26-27, 35, 48- 51, 55-56, 66-67, 79 -82 are rejected under 35 U.S.C. 103(a) as being unpatentable over by MacLeod ( 3,292,613) in view of Grahn ( 5,683,438) and Norton et al ( 3,878,839).

Note the comments above for the teaching of MacLeod.

Grahn teaches a device with vacuum pump 32, and heat exchanger 44, wherein the negative pressure is between – 20mmHg to – 85mmHg. Norton et al teaches a device with vacuum pump 85 ( figure 12) to provide pressure range from – 50mmHg to +25 mHg. In view of the teachings of Grahn and Norton et al , it would have been obvious to one ordinary skill in the art at the time the invention was made to provide the device of MacLeod with a heat exchanger to heat the circulating fluid , and to exhaust the air inside chamber 10 at the specified claimed negative pressures. As for claim 17, note that Grahn 's device is capable of providing these pressure ranges. As for claim 18 , note the valve 28 of Grahn.

Claims 19- 24, 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacLeod ( 3,292,613) in view of Grahn ( 5,683,438) and Norton et al ( 3,878,839), and further in view of McGarath ( 3,896,794) and Christoffel ( 4,186,732)

McGarath teaches a timer system 56. Christoffel teaches a pulse timer 13. In view of the teachings of McGarath and Christoffel, it would have been obvious to one ordinary skill in the art at the time the invention was made to provide the device of MacLeod with a timer system to bleed air at intervals for generating pulses of negative pressure. As for claims 20- 24, note that providing the teaching of MacLeod ( 3,292,613) wherein the pressure can be applied less frequently in regular multiples of a heartbeat ( i.e., in about at least more than one second , or longer), the exact optimum time intervals can be defined by obvious experiments and observations to provide optimum results, which are well within the realm of one ordinary skill in the art, and which do not provide any unexpected results, and therefore is not patentable over prior art.

Claim 39 -42 are rejected under 35 U.S.C. 103 as being unpatentable over MacLeod ( 3,292,613) in view of MacLeod (3,094,983 ), and further in view of Grahn( 5,683, 438).

Grahn teaches heating water at 43 degrees C. Note that the recited temperature is the results of obvious experiments and observations to provide optimum results, which is well within the realm of one ordinary skill in the art, and does not provide any unobvious result, and therefore are not patentable over prior art.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 47, 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Norton et al ( 3,878,839).

Norton et al teaches a pressure chamber 31 ( figure 6) into which the limb can be inserted, a barrier layer of flexible material 31 housed within that chamber for form-fitted engagement against the skin, the barrier layer defining an inner region within the pressure chamber for receiving the limb which is separated from a flow of liquid within the chamber, wherein the device includes an element or means for generating a pulsating pressure within the pressure chamber, and an element or means for generating a negative pressure between the barrier layer and the area of skin ( figure 14) to maintain the barrier layer in contact with the area of skin. Note column 9, lines 63-68, and column 10, lines 1-21. Therefore , Norton et al 's device is capable of providing the recited pressures .

### ***Response to Arguments6***

Applicant's arguments filed on 2/15/2007 have been fully considered but they are not persuasive. Note the comments relative to the claims above.

While applicant claims that negative pressure is generated for between 1 and 20 seconds and released for between 2 and 15 seconds, note that:

As for the MacLeod ( 3,292,613) 's patent, MacLeod ( 3,292,613) teaches that "the pressure can be synchronized to the heart beat or can be applied less or more frequently and in regular multiples of a heart beat , for example, during every second or third heart beat....., or the pressure can be applied irregularly with respect to the heartbeat."( column 5, lines 9-20). Therefore, the MacLeod patent teaches the recited negative pressure . Note that the rate of the heartbeat is different from one person to another. While the rate of the heartbeat of one person might be about every second or more , note that the rate of the heartbeat of another person (for example, a person who is sleeping , or in a state of relaxation, or in a meditation state , etc.) might be longer, or much longer than one second.

As for the Norton et al 's patent ( 3,878,839), note column 9, lines 63-68, and column 10, lines 1-21. Therefore , Norton et al teaches the recited negative pressure .

Also, note that a prima facie case of obviousness exists where the claimed ranges (or values ) and prior art ranges ( or values) do not overlap but are close enough that one skilled in the art would have expected them to have the same properties.

See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); and *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934. Also, see MPEP § 2131.03 for case law pertaining to rejections based on the anticipation of ranges under 35 U.S.C. 102 and 35 U.S.C. 102/103.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huong Q. Pham whose telephone number is (571) 272-4980. The examiner can normally be reached on 8:45 AM - 5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on ( 571) 272 - 4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

April 19, 2007

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4-30-07